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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,715	11/13/2003	Akira Suyama	14683Z	2123
23389 7590 06/01/2007 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER LU, FRANK WEI MIN	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,715	<b>Applicant(s)</b> SUYAMA ET AL.	
	<b>Examiner</b> Frank W. Lu	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's response to the office action filed on March 1, 2007 has been entered. The claims pending in this application are claims 17 and 19-25. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on March 1, 2007.

### ***Drawings***

2. The newly submitted Figures 9 and 13A filed on March 1, 2007 have been accepted by the office.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. New Matter

Claims 17-and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "amax=n; jmax and kmax $\geq$ n" is added to step (a) of the amended independent claim 17. However, the specification fails to define or provide any

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disclosure to support such claim recitation. Although the specification describes a flag consists of SD, D0, D1, and ED (see Figure 5) and the flag is modified (see page 6, first paragraph), the page 5, line 15 to page 16, line 5 of specification as suggested by applicant fails to define or provide any disclosure to support a three-unit structure consisting of SD unit, D0j unit, and ED unit as recited in the amended claim 20.

Although the specification describes that “[S]ince a complementary sequence to the target nucleic acid is bound inside the device, the target nucleic acid can be detected by binding the target nucleic acid to the complementary sequence” (see page 40, last paragraph), page 40, lines 18 of the specification and Figure 7B as suggested by applicant fails to define or provide any disclosure to support the phrase “step (g) is performed by sequences (D0j, D 1 k)’ complimentary to the flag sequences (D0j, D1k) immobilized to a DNA capillary” as recited in claim 21. Although the specification describes that “an orthonormal nucleotide sequence is used as each unit of the flag sequence FL” (see page 41, first paragraph) and SD, D0, D1, and ED are units of the flag sequence FL (see Figure 5), page 41, line 26 to page 42, line 2 of the specification as suggested by applicant fails to define or provide any disclosure to support the phrase “each of the units of the flag sequences (D0j, D1k) is an orthonormal nucleotide sequence” as recited in claim 24 since each of the units of the flag sequences (D0j, D1k) can be a single nucleotide and cannot be considered as SD, D0, D1, and ED.

MPEP 2163.06 notes “IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a

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departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application” .

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 17 is rejected as vague and indefinite in view of the phrase “a plurality of different target nucleic acids (N1, N2,...Nn)” because it is unclear that the contents of the square bracket are used to further limit the plurality of different target nucleic acids or are the parts of the plurality of different target nucleic acids. Please clarify.

9. Claim 17 is rejected as vague and indefinite in view of the phrase “each having a predetermined first partial sequence F and a predetermined second partial sequence S [(F1, S1), (F2, S2),... (Fn, Sn)] having a predetermined sequence in a specimen” because it is unclear that the contents of the square brackets are used to further limit the predetermined first partial sequence F and the predetermined second partial sequence S or are the parts of the predetermined first partial sequence F and the predetermined second partial sequence S. Please clarify.

10. Claim 17 is rejected as vague and indefinite in view of the phrase “probes Aa [A1, A2,... An] and probes Ba [B1, B2, ... Bn]” because it is unclear that the contents of the square brackets are used to further limit probes Aa and probes Ba or are the parts of probes Aa and probes Ba. Please clarify.

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11. Claim 17 is rejected as vague and indefinite in view of the phrase “flag sequence (D0j, D1k)” because it is unclear that the contents of the parentheses are used to further limit the flag sequence or are the parts of flag sequence. Please clarify.

12. Claim 17 is rejected as vague and indefinite in view of the phrase “each of which has a sequence F’a [F’1, F’2, ... F’n] complementary to the respective first partial sequence Fa [F1, F2,...Fn]” because it is unclear that the contents of the square brackets are used to further limit the sequence F’a and the first partial sequence Fa or are the parts of the sequence F’a and the first partial sequence Fa. Please clarify.

13. Claim 17 is rejected as vague and indefinite in view of the phrase “each of which has a sequence S’a [S’1, S’2, ...S’n] complementary to the respective second partial sequence Sa [S1, S2, ...Sn] of the target nucleic acid” because it is unclear that the contents of the square brackets are used to further limit the sequence S’a and the first partial sequence Sa or are the parts of the sequence S’a and the first partial sequence Fa. Please clarify.

14. Claim 17 is rejected as vague and indefinite in view of the phrase “ target nucleic acids (Fa, Sa) [F1, S1), (F1, S1), ... (Fn, Sn)]” in step b) because it is unclear that the contents of the square brackets are used to further limit the target nucleic acids or are the parts of the target nucleic acids. Please clarify.

15. Claim 17 is rejected as vague and indefinite in view of the phrase “preparing probes Aa [A1, A2,... An] and probes Ba [B1, B2, ... Bn] to convert target nucleic acids (Fa, Sa) into flag sequences (D0j, D1k)” in step (a) because this phrase does not make sense. Does this phrase mean preparing probes Aa [A1, A2,... An] and probes Ba [B1, B2, ... Bn] to amplify flag sequences (D0j, D1k) or mean something else? Please clarify.

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16. Claim 19 is rejected as vague and indefinite in view of step (f-1) because it is unclear that PCR in step (f-1) is identical to PCR in step (f) of claim 17 or not. If PCR in step (f-1) is identical to PCR in step (f) of claim 17, "PCR" in line 1 of step (f-1) should be the PCR. Furthermore, since claim 17 does not describe a first binding molecule, it is unclear how step (f-1) can have a second binding molecule. Please clarify.

17. Claim 22 recites the limitation "the first binding molecules" in the claim. There is insufficient antecedent basis for this limitation in the claim. Please clarify.

18. Claim 20 is rejected as vague and indefinite in view of the phrase "the D0j unit is assigned respectively to the target nucleic acids (Fa, Sa)". Does this phrase mean that the D0j unit is assigned to detect the target nucleic acids (Fa, Sa)" or mean something else? Please clarify.

### ***Response to Arguments***

19. Applicant's arguments with respect to claims 17-25 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. No claim is allowed.

22. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

May 24, 2007



FRANK LU  
PRIMARY EXAMINER